K072621

Cincinnati Sub-Zero Products, Inc.
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Cincinnati Ohio 45241-1528
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510K Summary

1. Owner's Name: Steve Berke
Address: Cincinnati Sub-Zero Products, Inc. (CSZ)
12011 Mosteller Rd.
Cincinnati, OH 45241
Phone: 513-772-8810
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DEC 1 3 2007

Contact: Fatma Ali, Director of Quality & Regulatory Affairs, CSZ

Organization Number: **84901**

Establishment: **New Device**

Registration Number: **1516825**

Operations: **Manufacturer and Specification Developer**

Date: **Monday, December 03, 2007**

2. Name of the Devices:

- **Esophageal/Rectal Temperature Probe, and**
- **Esophageal Stethoscope With Temperature Sensor Probe**

Probes trade/proprietary name: **THERMA-TEMP, STERI-PROBE**

Common name: **Temperature Probe**

Classification: **Esophageal Rectal and Esophageal Stethoscope, with Electrical Conductors**

Product Code: **BZT**

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3. **Predicate Devices:**

- **Smiths Level 1 Esophageal/Rectal Temperature Probe; and**
- **Esophageal Stethoscope With Temperature Sensor Probe**

Both devices are originally, listed under Respiratory Support Products, Inc. as referenced in 510K Number's: K864043 & K864044

4. **Device Description:**

Disposable Temperature Probes using thermistors as temperature sensors. The signal of the sensor is processed and displayed by the monitoring unit.

5. **Intended Use:**

Continuous measurement of core body temperature through the esophagus or the rectum.

6. **Comparison to the Predicate Device:**

The CSZ Esophageal/Rectal Probes and Esophageal Stethoscope are substantially equivalent to the Smiths Level 1 Esophageal/Rectal Probes and Esophageal Stethoscope.

7. **Discussion of Non-clinical Tests performed:**

Testing was done in accordance with BS EN 12470-4, Clinical Thermometers.

8. **Conclusion:**

The CSZ Esophageal/Rectal Probe and Esophageal Stethoscope have the same intended use and technological characteristics as the cleared devices (Smiths Level 1 Esophageal/Rectal Probes and Esophageal Stethoscope). The performance testing has shown that the CSZ products included in this pre-market submission meet the requirements of EN 12470-4 for Clinical Electronic Thermometers, and therefore maintain the same levels of safety and effectiveness as the predicate device currently in commercial distribution.

I certify that, in my capacity as the Director of Quality and Regulatory Affairs of Cincinnati Sub-Zero Products Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

S. Ali

Date: 12/3/07

Fatma Ali
Director of Quality and Regulatory Affairs
Cincinnati Sub-Zero
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

Ms. Fatma Ali
Director of Quality & Regulatory Affairs
Cincinnati Sub-Zero Products, Incorporated
12011 Mosteller Road
Cincinnati, Ohio 45241

Re: K072621
Trade/Device Name: Esophageal/Rectal Temperature Probe and Esophageal Stethoscope with Temperature Sensor
Regulation Number: 21 CFR 868.1920
Regulation Name: Esophageal Stethoscope with Electrical Conductors
Regulatory Class: II
Product Code: BZT
Dated: December 4, 2007
Received: December 6, 2007

Dear Ms. Ali:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use

510(k) Number (if known):

Unknown

Device Name(s):

Esophageal/Rectal Temperature Probe, Catalog Numbers 483M-9, 483M-12, and 491B

Esophageal Stethoscope with Temperature Sensor, Catalog Numbers 493M-9, 493M-12, 493M-18, and 493M-24

Indications for Use:

Esophageal/Rectal Temperature Probe, Catalog Numbers 483M-9, 483M-12, and 491B: The CSZ esophageal/rectal temperature probe is intended for use in routine continuous monitoring of the esophageal or rectal temperature as an indicator or core body temperature. The probe is designed for placement in the esophagus or rectum.

Esophageal Stethoscope with Temperature Sensor, Catalog Numbers 493M-9, 493M-12, 493M-18, and 493M-24: The CSZ esophageal stethoscope with temperature sensor is intended for use when the esophageal temperature is continuously monitored along with the auscultation of the heart and lung sound as an indicator of core body temperature and cardio-pulmonary performance.

Prescription Use: XXXX and/or Over-the-Counter Use: ____

(Part 21CFR801 Subpart D) (Part 21CFR801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K973621